

510(k) SUMMARY
RNK Products, Inc.
PPA/BT-RB Stethoscope

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K132405

Submitter Information

Submitter: RNK Products, Inc.
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Viera, FL 32940
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OCT 11 2013

Contact Person: Charles R. Abbruscato
Date Prepared: October 9, 2013

Device Information

Name of Device RNK PPA/BT-RB Stethoscope
Common or Usual Name Electronic Stethoscope
Classification Name Electronic Stethoscope
Predicate Devices RNK Electronic Stethoscope (K072026)

Device Description

The RNK PPA/BT-RB Stethoscope is comprised of a PCP Chest Piece assembly, an Amplifier Module containing an amplifier which amplifies the signal from the PCP Chest Piece and a Bluetooth wireless transmitter, and a standard audio Headset, plus an optional Bluetooth Headset.

The PCP Chest Piece assembly includes an attached cable terminated in a standard 3.5 mm audio stereo plug, which plugs into the Chest Piece port of the Amplifier Module. A standard, off-the-shelf Headset with a 3.5 mm stereo audio plug can plug into the Headset port of the Amplifier Module to enable a listener to hear the amplified sounds from the PCP Chest Piece. Optionally, an off-the-shelf Bluetooth Headset can be used to listen to the signal from the PCP Chest Piece over a Bluetooth connection to the Bluetooth transmitter in the Amplifier Module.

The RNK Amplifier is powered by x2 AAA NiMH batteries, which can be recharged from a wall mount 5vdc power supply with a micro-USB connector. The Amplifier Module is not functional as a stethoscope while the batteries are being charged.

The RNK PPA/BT-RB Stethoscope provides up to about 20 times greater amplitude signal than a typical acoustic stethoscope. The overall auscultation frequency response of the RNK PPA/BT-RB Stethoscope is 20 Hz – 1,500 Hz.

Intended Use

The RNK PPA/BT-RB Stethoscope is intended for use in detecting and amplifying heart, lung and other body sounds for diagnostic or monitoring purposes on a patient.

Substantial Equivalence

The RNK PPA/BT-RB Stethoscope is substantially equivalent to the RNK Electronic Stethoscope (K072026). Both use the PCP Chest Piece and the PPA/BT-RB Amplifier Module uses the same amplifier circuit and the same enclosure as the predicate device.

Both the PPA/BT-RB Stethoscope and the predicate device successfully demonstrated conformance to IEC60601-1:2005 3rd Edition Medical Electrical Equipment Part 1: General Requirement for Safety and to EN60601-1-2, 2007/03, EMC Immunity Requirements for Medical Electrical Equipment Part 1: General Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests. Since both devices use the same materials that a patient or clinician might touch, the Biocompatibility Analysis is the same. The PPA/BT-RB Stethoscope passed the same auscultation performance tests as the predicate device both in bench testing and by clinicians.

The RNK PPA/BT-RB Stethoscope has the same intended use, principles of operation and technological characteristics as the auscultation function of the predicate device. There are no new questions of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 11, 2013

RNK Products, Inc.
c/o Mr. Charles Abbruscato
C.E.O.
8247 Devereux Dr., Suite 101
Melbourne, FL 32940 US

Re: K132405
Trade/Device Name: PPA/BT-RB Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 29, 2013
Received: August 30, 2013

Dear Mr. Charles Abbruscato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, Ph.D.

Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132405

Indications for Use

510(k) Number (if known): K132405

Device Name: RNK PPA/BT-RB Stethoscope

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X
(Per CRF 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)